REMARKS/ARGUMENTS

Claims 1-13 and 15-27 are pending in the application. Applicants note with appreciation that the Examiner has indicated that claims 20 and 21 would be allowable if rewritten in independent form. Claims 15, 16, 26, and 27 are currently withdrawn.

Claims 1-13, 17-19, and 22-24 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,607,687 to Bezwada *et al.* Applicants respectfully traverse this rejection.

Bezwada *et al.* describe polyoxaesters. These polyesters are blended with a second polymer and said second polymer is not intended to react with the polyoxaester. The polymer blends may be used to produce surgical devices such as sutures, sutures with attached needles, clips, staples, and the like. The polymer blends are bioabsorbable and may be processed in numerous ways, e.g., by melt processing, molding and solvent casting.

In contrast, the present invention discloses chemically cross-linked poly(ethylene glycol) hydrogels (PEG-hydrogels) that degrade in a predictable manner. Weak chemical linkages, e.g., carboxylate ester linkages, are introduced into the hydrogel and provide, in combination with the degree of cross-linking, for the hydrolytic degradation of the hydrogel and the releases of drug molecules that can be trapped within the hydrogel. The hydrogels are broken down to substantially nontoxic PEG-fragments which are usually cleared from the body.

The subject-matter of independent claim 1 is directed to a cross-linked polymeric structure in the form of a hydrogel that swells in water. The polymeric structure includes PEG-polymers. Non-PEG polymers are not present. Hydrolytically unstable linkages provide for the degradability.

It is further noted that the polyoxaester disclosed in Bezwada *et al.* are substantially linear polymeric molecules. The addition of coupling agents causes branching of long chains, which can impart desirable properties in the molten state to the polyester pre-polymer (column 4, lines 52 to 60). The consequence of introducing a certain degree of branching is the reduction of gelation. In addition, the decrease in viscosity is intended to improve further processing.

Branching only means that a polymer chain is not linear but has one or more side-chains, while crosslinking means that two (parallel) polymer chains are connected by connecting

molecules. This difference is important because cross-linking, as it is achieved in hydrogels according to the present invention, does not allow further processing.

The cross-linked polymeric structures of the present invention undergo extensive swelling in an aqueous environment. In contrast, the polyoxaesters disclosed in Bezwada *et al.* are hydrophobic and therefore do not undergo swelling when they come in contact with water. Further, swelling is highly undesirable in suture material. As a consequence of the swelling in an aqueous environment, for hydrogels according to the present invention, degradation proceeds throughout the whole hydrogel. Polyoxaester materials as taught in Bezwada *et al.* are only degraded on their surface, which greatly reduced their bio-absorbability.

In contrast to the Bezwada disclosure, the hydrolytic degradation of hydrogels of the present invention can be precisely controlled by the degree of crosslinking, by altering the number of methylene groups adjacent to the hydrolytically unstable linkage, and by altering the degree of branching of the PEG polymer (page 6, paragraph [0030] of the specification). For instance, the half life of an ester linkage with one adjacent ethylene group is about four days at pH=7 and 37°C (page 6, paragraph [0029] of the specification). Bezwada *et al.* do not describe in any way how the degradability of the polymeric materials may be controlled.

In hydrogels according to the present invention, non-PEG polymers are absent, since it is known that non-PEG elements tend to introduce complexity into the hydrogel and the degradation of the matrix can yield undesirable or toxic components that are released into the blood stream when the hydrogels are used *in vivo* for drug delivery (page 4, paragraph [0021] of the specification). Since there are no non-PEG polymers present, the hydrogels advantageously break down to substantially non-toxic PEG fragments that are typically cleared from the body (page 5, paragraph [0023] of the specification).

In sum, Bezwada *et al.* teach polymer blends containing two polymers that are <u>not cross-linked</u>. The polymers may comprise PEG components, but the Bezwada patent does not disclose <u>hydrogels</u>. In fact, it is clear that Bezwada *et al.* do not suggest cross-linked polymeric structures forming a hydrogel in any way. Therefore, the subject matter of claim 1, and all claims dependent thereon, is novel over Bezwada *et al.*

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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